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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,042	07/03/2001	Rudolf Valenta	1614-0251P	5581
2292 7	590 07/29/2002			
BIRCH STEV	VART KOLASCH &	EXAMINER		
PO BOX 747		NOLAN, PATRICK J		
FALLS CHUR	CH, VA 22040-0747	NOEMN, I	TIMORY	
			ART UNIT	PAPER NUMBER
			1644	
			DATE MAILED: 07/29/2002	4

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No. 09/897,042 Applicant(s)

Valenta et al.

Examiner

Patrick J. Nolan

Art Unit 1644



1

	The M	IAILING DATE of this communication app	pears on the cover sh	eet with	the correspondence address		
	for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.							
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.							
<ul> <li>If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>							
Status							
1) 💢	Respons	sive to communication(s) filed on <u>May</u>	15, 2002		·		
2a) 💢	This act	ion is <b>FINAL</b> . 2b) ☐ Th	is action is non-final	l <b>.</b>			
3) 🗆	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.						
Disposi	tion of Cl	aims					
4) 🗶	Claim(s)	1-6, 8, 9, and 14-27			is/are pending in the application.		
4	a) Of the	e above, claim(s) <u>8, 9, 14-20, 23, and</u>	24	<u>-</u>	is/are withdrawn from consideration.		
5) 🗆	Claim(s)				is/are allowed.		
6) 💢	Claim(s)	1-6, 21, and 22			is/are rejected.		
7) 💢	Claim(s)	25-27	-		is/are objected to.		
8) 🗆	Claims _		are	subject	to restriction and/or election requirement.		
Application Papers							
9) 🗆	The spec	cification is objected to by the Examin	er.		·		
10)	10) The drawing(s) filed on is/are a) accepted or b) objected to by the Examiner.						
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11)	The prop	posed drawing correction filed on	is	: a)□ a	pproved b) $\square$ disapproved by the Examiner.		
	If approved, corrected drawings are required in reply to this Office action.						
12)	12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120							
13)□	13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) 🗀	a) 🗆 All b) 🗀 Some* c) 🗀 None of:						
	1. Certified copies of the priority documents have been received.						
	2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).							
*See the attached detailed Office action for a list of the certified copies not received.							
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).							
a) The translation of the foreign language provisional application has been received.							
15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachm		Cited (PTO 903)	4) []		(412) Penns No(a)		
_		nces Cited (PTO-892)			Application (PTO-152)		
_	2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6) Other:						
<b>→,</b> □	J						

Application/Control Number: 09/897,042

Art Unit: 1644

#### **DETAILED ACTION**

- 1. Claims 1-6, 8-9, and 14-24 and newly added claims 25-27 are pending.
- 2. Claims 8-9, 14-20, and 23-24 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a non-elected invention.
- 3. Claims 1-6 and 21-22 and 25-27 are under consideration in the instant application.

## Claim Rejections - 35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-6 and 21-22 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments filed 5-15-02 have been fully onsidered but are not found persuasive.

Applicant argues they can recirte their claims as is well recognized by those in the art.

However, The claim would be more definite if it read "said fragment comprising an IgG epitope and an IgE epitope partly but not completely ".

#### Claim Rejections - 35 USC § 102 and Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in

Art Unit: 1644

order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

- 5. Claims 1-2, 4, and 6 stand rejected under 35 U.S.C. 102(b) as being anticipated by Rogers et al. (Molecular Immunology, 1994; 31(13): 955-966), for reasons set forth in Paper No. 7.
- 6. Claims 3 and 21 are rejected under 35 U.S.C. 103 as being unpatentable over Rogers et al. (Molecular Immunology, 1994; 31(13): 955-966), in view of U.S. Patent 4,629,783.
- 7. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. (Molecular Immunology, 1994; 31(13): 955-966) in view of U.S. Patent 4,629,783 as applied to claim 21 above, and further in view of U.S. Patent 6,126,939.

Applicant's arguments filed 5-15-02 have been fully considered but are not found persuasive.

Applicant argues that since Roger's et al., does not teach an IgG epitope, it does meet the claim limitations.

However, Applicant is guided to MPEP section 2112 which discloses that once the office has established the prior art is substantially similar to the claimed invention, the burden shifts to Applicant to demonstrate the differences. In other words the burden is on Applicant to demonstrate all of the peptides

disclosed by Rogers to be non-anaphylactic and not contain an IgE epitope do not contain an IgG epitope.

- 8. Claims 1-2 and 4-5 stand rejected under 35 U.S.C. 102(a) as anticipated by Vrtala et al. (J. Clin. Invest. 1997 April; 99(7): 1674-1681), for reason set forth in Paper No. 7.
- 9. Claims 1-2 and 4-6 are rejected under 35 USC 103 as being unpatentable over Vrtala et al. (J. Clin. Invest. 1997 April; 99(7): 1674-1681) in view of U.S. Patent 4,269,764.
- 10. Claims 3 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vrtala et al. (J. Clin. Invest. 1997 April; 99(7): 1674-1681) in view of U.S. Patent 4,269,764 as applied to claims 1, 2, 4, and 6 above, and further in view of U.S. Patent 4,629,783.

Applicant states a 37 CFR 1.132 declaration is forthcoming. The rejections are maintained.

- 11. Claims 25-27 are objected to as being dependent upon rejected claims.
- 12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Application/Control Number: 09/897,042

Art Unit: 1644

- 13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Thursday from 9:30 am to 4:30 pm.
- 14. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

7/27/02